

### **DETAILED ACTION**

Applicants' Amendment to the Claims filed on 12 April 2011 is acknowledged.

Claims 2, 6-7, 12, 17-43 and 45-48 are cancelled. Claim 55 is new. Claims 1 and 44 are currently amended. Claims 1, 3-5, 8-11, 13-16, 44 and 49-55 are pending and under examination.

#### ***Response to Amendment***

Any/all objections and rejections to cancelled claim 12 are moot.

The rejection of claims 11, 13, 14, 15 16, 49-51 and 54 under 35 U.S.C. 112, second paragraph, is WITHDRAWN based on claim amendments filed on 4/12/2011.

The rejection of claims 1, 3-5, 8-11, 13-16, 44 and 49-54 under 35 U.S.C. 103(a) as being unpatentable over Liggins & Burt in view of Mahato et al and further in view of Lollo et al is WITHDRAWN based on claim amendments filed on 4/12/2011.

#### ***New grounds of rejection necessitated by amendment***

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Currently amended claims 1, 3-5, 8-11, 13-16, 44 and 49-55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

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application was filed, had possession of the claimed invention. This rejection is a **NEW MATTER** rejection. *This is a new rejection necessitated by Applicant's amendment.*

The specification as originally filed does not provide support for the invention as now claimed: “a polyester backbone comprising N-methyldietheneamine sebacate **and/or** [(cholesteryl oxocarbonylamido ethyl) methyl bis (ethylene) ammonium bromide] sebacate”. Specifically, base claims 1 and 44 currently recite the claim language “and/or” and thus the claims now are drawn to the following three distinct types of polyester backbones:

- (i) a polyester backbone comprising N-methyldietheneamine sebacate *without* [(cholesteryl oxocarbonylamido ethyl) methyl bis (ethylene) ammonium bromide] sebacate,
  - (ii) a polyester backbone comprising N-methyldietheneamine sebacate *and* [(cholesteryl oxocarbonylamido ethyl) methyl bis (ethylene) ammonium bromide] sebacate,
- and
- (iii) a polyester backbone comprising [(cholesteryl oxocarbonylamido ethyl) methyl bis (ethylene) ammonium bromide] sebacate *without* N-methyldietheneamine sebacate.

The specification does not provide sufficient blazemarks nor direction for the above type (iii), a polyester backbone comprising [(cholesteryl oxocarbonylamido ethyl) methyl bis (ethylene) ammonium bromide] sebacate ***without*** N-methyldietheneamine sebacate. The instant claims now recite limitations, which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in the present claims, which did not appear in the specification as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

### ***State of the art***

The specific embodiment of an article for delivering a drug and a nucleic acid, the article comprising: (i) a nanoparticle forming a micelle, wherein the nanoparticle comprises a polymer

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having a polyester backbone comprising N-methyldietheneamine sebacate and [(cholesteryl oxocarbonylamido ethyl) methyl bis (ethylene) ammonium bromide] sebacate; (ii) a nucleic acid associated with an exterior of the micelle; and (iii) a drug associated with an interior of the micelle appears to be non-obvious and free of the prior art.

### ***Conclusion***

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine Hibbert whose telephone number is (571)270-3053. The examiner can normally be reached on M-F 8AM-5PM, EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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